THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: GIBSON, Glenn R. et al.	Confirmation No.: 7110
Application No.: 10/721,652	Group Art Unit: 1615
Filing Date: November 25, 2003	Examiner: BARHAM, Bethany P.
For: PREBIOTIC COMPOSITIONS	Attorney Docket No.: 8497-US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S APPEAL BRIEF

Sir:

Appellant submits this Appeal Brief in support of the Notice of Appeal filed on January 6, 2010. This Appeal is taken from the Final Rejection in the Office Action dated October 16, 2009.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec, S.A. by virtue of an Assignment dated February 28, 2008 and recorded at reel 020571, frame 0616 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellant's legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1, 6-8, 10-11 and 26-27 are pending in the above-identified patent application. Claims 2-5, 9 and 12-25 were previously canceled without prejudice or disclaimer. Claims 1, 6-8, 10-11 and 26-27 stand rejected. Therefore, Claims 1, 6-8, 10-11 and 26-27 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Non-Final Office Action was mailed on May 13, 2009 in which the Examiner rejected Claims 1, 6-8, 10-11 and 26 under 35 U.S.C. §112, first paragraph, and Claim 27 under 35 U.S.C. §103. Appellant filed a Response to the Non-Final Office Action, in which Appellant amended independent Claim 27 and argued against the enablement and obviousness rejections. A Final Office Action was mailed on October 16, 2009, in which the Examiner maintained the rejections. An Advisory Action was mailed by the Examiner. Appellant filed a Notice of Appeal on January 6, 2010. A copy of the Non-Final Office Action and the Final Office Action are attached as Exhibits A and B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a composition comprising an oligosaccharide blend that comprises fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS) (page 7, lines 26-31), wherein (a) the composition comprises from about 15 g to about 20 g of the oligosaccharide blend (page 7, lines 7-12); (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7 (page 5, line 1-page 6, line 18); (c) the weight ratio of FOS and GOS is from about 0.5 to about 20 (page 9, lines 1-5); and (d) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties (page 3, lines 17-26).

Independent Claim 27 is directed to a composition comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS) (page 7, lines 26-31), wherein each of said FOS and GOS contains up to 95% by weight of said oligofructose (page 5, lines 20-25) and said oligogalactose that are composed of chains with a degree of polymerization ranging from about 2 to about 7 (page 5, line 1-page 6, line 18) and wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 (page 9, lines 1-5) and wherein the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties(page 3, lines 17-26).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for

circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 6-8, 10-11 and 26 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirements.

2. Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,399,124 to Lesens et al. ("*Lesens*") in view of U.S. Publication No. 2003/0138476 to Van Leeuwen et al. ("*Van Leeuwen*"). Copies of *Lesens* and *Van Leeuwen* are attached herewith as Exhibits C and D, respectively, in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

1. Enablement under 35 U.S.C. § 112, first paragraph

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also, *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

2. Obviousness under 35 U.S.C. § 103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made…The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art…Moreover, objective indicia such as commercial success and long felt need are relevant

> to the determination of obviousness…Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 837 F.2d 1071, 5, U.S.P.Q.2d 1596 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Finally, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q., 580 (CCPA 1974).

Further, the Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Moreover, the Federal Circuit has held that "obvious to try" is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). "An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued." *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE CLAIMED INVENTION

Independent Claim 1 is directed to a composition comprising an oligosaccharide blend that includes fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS). The composition includes from about 15 g to about 20 g of the oligosaccharide blend and each of the oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7. The weight ratio of FOS and GOS is from about 0.5 to about 20, and the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.

Independent Claim 27 is directed to a composition including glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS). The FOS and GOS contains up to 95% by weight of the oligofructose and the oligogalactose that are composed of chains with a degree of polymerization ranging from about 2 to about 7. The weight ratio of FOS and GOS is from about 0.5 to about 20 and the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.

C. CLAIMS 1, 6-8, 10-11 AND 26 SATISFY THE ENABLEMENT REQUIREMENT UNDER 35 U.S.C. §112, FIRST PARAGRAPH

1. The Claimed Invention and Its Surprising Results

Independent Claim 27 recites, in part, a composition comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*. In contrast, the cited references fail to disclose or suggest each and every element of independent Claim 27.

As discussed above, the present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, the present invention has shown that the prebiotic properties of FOS as significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention.

Additionally, results from the Examples in the specification clearly show that the combination of FOS and GOS acts synergistically and enhances surprisingly the bifidobacteria and lactobacilli to higher amounts than when these oligosaccharides were tested alone. The less beneficial bacteria seem to not be influenced by the combination towards a reduction in numbers, but rather increased slightly, as compared to both oligosaccharides tested separately. The are especially good prebiotics due their property to enhance growth selectively. The combination of FOS and GOS, when compared to all ingredients and combination tested, to be the best prebiotic ranking over the entire fermentation period. See, specification, page, 20, line 32-page 21, line 3. In contrast, Appellant respectfully submits that *Lesens* and *Van Leeuwen* fail to disclose each and every limitation of the present claims.

2. The Claimed Invention is Fully Enabled by the Specification

In the Office Action, Claims 1, 6-8, 10-11 and 26 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner alleges that "Applicants do not describe th[e] invention in such a manner that would enable one of ordinary skill in the art to use th[e] invention at the higher claimed range of about 15 to about 20 g [of an oligosaccharide blend] without undue burden." See, Final Office Action, page 2.

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also, *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

Appellant respectfully submits that because the breadth of the claimed invention is clear, the skilled artisan would be able to practice the claimed invention (i.e., make the claimed composition) without undue experimentation. Claim 1 recites a composition comprising an oligosaccharide blend that comprises fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein (a) the composition comprises from about 15 g to about 20 g of the oligosaccharide blend; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.

The suitable range of FOS and GOS is clearly defined and can be used in any amount in the composition from about 15 g to about 20 g. The types of FOS and GOS are clearly defined in (b). The weight ratio of FOS and GOS are clearly defined in (c). Element (d) recites the characteristics that the combination of FOS and GOS provide when added to the composition to meet the requirements of (a), (b) and (c). As a result, the skilled artisan would be able to practice the claimed invention without undue experimentation because the skilled artisan has clearly defined parameters to use when making the claimed composition comprising the recited oligosaccharide blend.

The Examiner states that "'measuring 20g or 15g of fiber is not at issue as the enablement rejection at issue is solely based on 'use [of] this invention at the higher claimed range of about 15 to about 20g[] without undue burden' and the disclosure of the amount for 20g or 15g of oligosaccharide blend does not render that amount 'useful.'" See, Final Office Action, page 10, lines 9-13. Appellant submits that this is clearly a misinterpretation of the standard for enablement.

The present claims are directed to "compositions." Further, "[t]he test of enablement is whether one reasonably skilled in the art could *make* or *use* the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." See, *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (emphasis added). Thus, the standard does not require that the skilled artisan both make and use the claimed compositions. Instead, since the present claims are directed to compositions, and not methods of administering the compositions, Appellant submits that it is entirely irrelevant what biological processes may occur in the human body after administration of the claimed compositions to, for example, "leave an unpleasant feeling of heaviness in the stomach" of a consumer, as is alleged by the Examiner. Indeed, once issued, the present claims may be infringed by a potential infringer for simply making the compositions.

Further, the Examiner also asserts that "the fact that other patents have drugs that 'can cause adverse side effects' is not pertinent to this case, what is pertinent is that the prior art '124 teaches that a composition above 10g of fiber is not useful." See, Final Office Action, page 10, lines 18-20. In contrast, Appellant submits that the prior art does not state that the administration of more than 10 g of fiber is "not useful." Instead, the prior art allegedly teaches that "higher quantities [than 10 g of fiber] in a dessert leave an unpleasant feeling of heaviness in the

stomach," as stated by the Examiner. See, Final Office Action, page 11 (emphasis added). The Examiner's argument is analogous to the composition Syrup of Ipecac. While Syrup of Ipecac is extremely useful in that it induces vomiting when necessary (e.g., for poison control), which most likely causes an "unpleasant feeling," the simple fact that it creates an "unpleasant feeling" does not mean that the composition is not "useful" for its intended purpose (i.e., inducing vomiting).

Moreover, Appellant respectfully submits that compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. An applicant need not have actually reduced the invention to practice prior to filing. See, MPEP 2164.02. Therefore, Appellant respectfully submits that, even if the Examiner is correct that there are no working examples that describe the use of from about 15 g to about 20 g of an oligosaccharide blend, such a requirement is not necessary. The present disclosure is still enabling because Appellant has provided a prophetic example of the claimed composition comprising from about 15 g to about 20 g of the oligosaccharide blend.

To support Appellant's proposed claims, the specification also specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, Appellant has surprisingly found the prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention.

With respect to the state of the prior art, the Examiner alleges that "[t]he art teaches that a single composition should not contain more than 10 g of fiber and Applicant['s] instant Examples do not contain more than 10g of fiber." The Examiner also states that "[i]t is clear from the prior art above that amounts in a single composition above 10g give discomfort to a person." See, Final Office Action, page 4. However, Appellant respectfully submits that the Examiner mischaracterizes the nature of the claimed invention and the scope of the prior art.

As discussed above, the present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, Appellant has shown that the prebiotic properties of FOS as significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. This utility is not considered by the prior art. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention, which overcome the problems discussed by the prior art.

Moreover, Appellant respectfully submits that simply because the prior art allegedly discloses that too much fiber may cause discomfort does not make the presently claimed subject matter un-enabled. Appellant notes that the prior art does not disclose or suggest that a specific oligosaccharide blend of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS) may cause discomfort. In fact, the prior art only states that too much fiber may cause discomfort. As a result, the prior art has not even considered the beneficial effects of the oligosaccharide blend in accordance with the present blends. The prior art fails to even consider that there may be combinations of fibers that do not provide discomfort despite the assertion by the Examiner.

Additionally, the enablement requirement requires only that practicing the claimed invention not be unduly burdensome for the skilled artisan. It does not require that administration of a composition results in no adverse side effects. In fact, many patented drugs,

pharmaceuticals and nutritional supplements can cause adverse side effects. Therefore, while Appellant does not admit that administration of the presently claimed compositions may cause discomfort and, in fact, submits that the opposite is true and the presently claimed compositions result in synergistic effects in promoting the growth of beneficial bacteria, Appellant submits that it is irrelevant whether the prior art indicates that more than 10g of fiber may cause discomfort. Indeed, such a teaching would actually lead the skilled artisan down a path divergent from the presently claimed subject matter in view of such a disclosure. Accordingly, the prior art would actually teach away from the presently claimed subject matter.

Finally, with respect to the quantity of experimentation, the Examiner continues to assert that "a burdensome amount of research would be required by one of ordinary skill in the art to bridge [the] gap" between a composition comprising 2g, 2.5g, and 9.86g and a composition comprising about 25g, about 20g or about 15g of fiber. See, Final Office Action, page 6, line 19-page 7, line 1. However, Appellant respectfully disagrees. Instead, as previously discussed, Appellant notes that specific amounts of specific ingredients for use in the present compositions are clearly set forth in the specification. Among those specific amounts of ingredients, a composition comprising from about 15 g to about 20g of fiber is clearly set forth in the specification.

Accordingly, because the Examiner admits that the relative skill of those in the art is very high (e.g., Ph.D and M.D. level technology), Appellant respectfully submits that the skilled artisan would be more than capable of measuring from about 15 g to about 20 g of fiber to include in a composition comprising both FOS and GOS in the presently claimed ratios and test whether this amount provided a synergistic effect over individual FOS, GOS or other oligosaccharide. Indeed, the relative skill of a Ph.D or an M.D. is not even required to be able to create a composition according to the present claims that include from about 15 g to about 20 g of the oligosaccharide blend. Rather, anyone capable of adding FOS and GOS to a composition in an amount required by (a), (b) and (c) can practice the claimed invention.

For at least these noted reasons, Appellant respectfully submits that the present claims are fully enabled by the specification and would not require a burdensome amount of experimentation for the skilled artisan to obtain compositions according to the present claims.

Accordingly, Appellant respectfully submits that Claims 1, 6-8, 10-11 and 26 fully comply with 35 U.S.C. §112, first paragraph, and are in condition for allowance.

D. THE REJECTION OF CLAIM 27 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellant also respectfully submits that the obviousness rejection of Claim 27 should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness. In the Final Office Action, the Examiner maintained that the combination of *Lesens* in view of *Van Leeuwen* renders the claimed subject matter obvious. See, Final Office Action, pages 6-14. However, the Examiner has failed to establish a *prima facie* case of obviousness because the cited references fail to disclose or suggest each and every element of the present claims. Moreover, the claimed invention provides surprising results that would have overcome any *prima facie* obviousness rejection.

As discussed above, independent Claim 27 recites, in part, a composition comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*. Appellant submits that *Lesens* and *Van Leeuwen* fail to disclose or suggest each and every element of independent Claim 27.

Lesens and *Van Leeuwen* alone or in combination fail to disclose or suggest compositions comprising glutamine and an oligosaccharide blend as required, in part, by Claim 27. *Lesens* and *Van Leeuwen* alone or in combination also fail to disclose or suggest an oligosaccharide blend that consisting essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS) having a weight ratio from about 0.5 to about 20 as required, in part, by Claim 27.

Lesens is entirely directed to frozen desserts that contain lactic acid bacteria and dietary fibers and its benefit to the human health after consumption of the frozen desserts. *Lesens* fails to disclose or suggest the use of glutamine at any place in the disclosure. Such a bioactive compound is known to have health benefits, especially with respect to the gastrointestinal tract. Further, *Lesens* also fails to disclose or suggest compositions having an oligosaccharide blend consisting essentially of FOS and GOS at the weight ratio in accordance with independent Claim 27. Instead, *Lesens* discloses compositions having either FOS or GOS, but not both and not at

the claimed ratio. Indeed, the Examiner fails to point to any specific disclosure in *Lesens* with respect to these elements. As a result, *Lesens* fails to recognize the advantages, benefits and/or properties of the claimed oligosaccharide blend in accordance with the present claims.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to make a composition of FOS and GOS in a specific ratio. As support for this statement, the Examiner asserts that "Examples 4-5 of *Lessens* et al teach a cone made of Raftilose L30 (table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). However, the Examples cited by the Examiner as disclosing the use of either FOS or GOS do not even use the FOS and GOS in the same compositions, let alone the FOS and GOS used in the same compositions as an oligosaccharide blend. At best, *Lesens* discloses that an aerated ice creams may be dipped into compositions having GOS (Table 3) or FOS (Table 4), or that ice cream may be contained in a wafer dough containing FOS (Examples 4-5) or GOS (Example 5). At no place in the disclosure does *Lesens* disclose the use of FOS and GOS in an oligosaccharide blend. In fact, *Lesens* never discloses that the FOS and GOS are used in the same composition, let alone as an oligosaccharide blend of a specific amount, or as an oligosaccharide blend consisting essentially of those two oligosaccharides as required, in part, by independent Claim 27.

The Examiner also continues to assert that *Lesens* teaches "both galacto-oligosaccharides and fructooligosaccharides" and "mixtures thereof." See, Final Office Action, page 11, lines 17-21. However, Appellant submits that this misinterprets the disclosure of *Lesens* when taken as a whole. For example, claim 26 is the only place in *Lesens* where any "mixture" of fibers is disclosed. However, Appellant respectfully submits that the only reason the phrase "mixtures thereof" is used in *Lesens* is because it is commonly used with markush groups. Indeed, at no place in the disclosure does *Lesens* disclose the use of FOS and GOS in an oligosaccharide blend. Accordingly, the disclosure of Lesens fails to provide support for "mixtures" of the presently claimed oligosaccharides.

Additionally, in contrast to the Examiner's assertion, column 4, lines 56-64 does not disclose mixtures of GOS and FOS, as required, in part, by independent Claim 27. Instead, column 4, lines 56-64 discloses "preferred galactooligosaccharides" and "preferred fructooligosaccharides." Further, the paragraph immediately preceding this disclosure discloses that the fibers may be, for example, "fructo-, . . . galacto-, . . . or xylo-oligosaccharides, or soya

beans . . . or resistant starches, or products high in ß-glucans." See, *Lesens*, col. 4, lines 44-51 (emphasis addedAs discussed above, the Examples cited by the Examiner as disclosing the use of either FOS or GOS do not even use the FOS and GOS in the same compositions, let alone the FOS and GOS used in the same compositions as an oligosaccharide blend. At best, *Lesens* discloses that an aerated ice creams may be dipped into compositions having GOS (Table 3) or FOS (Table 4), or that ice cream may be contained in a wafer dough containing FOS (Examples 4-5) or GOS (Example 5).

Van Leeuwen is directed to the use of glutamic acid for the preparation of a nutritional preparation that is intended for use for the treatment or prevention of excess or undesired permeability of the intestinal wall. *Van Leeuwen* specifically fails to disclose or suggest compositions having an oligosaccharide blend consisting essentially of FOS and GOS at the weight ratio in accordance with independent Claim 27. Instead, *Van Leeuwen* discloses compositions having either FOS or GOS, but not at the claimed ratios. Indeed, the Examiner fails to point to any specific disclosure in *Van Leeuwen* with respect to the recited elements.

For at least these noted reasons, *Lesens* and *Van Leeuwen* alone or in combination fail to disclose suggest each and every element of independent Claim 27. Moreover, *Lesens* and *Van Leeuwen* fail to recognize the advantages, benefits and/or properties of the claimed oligosaccharide blend in accordance with the present claims.

Accordingly, Appellant respectfully requests that the obviousness rejection of Claim 27 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

VIII. CONCLUSION

Appellant respectfully submits that Claims 1, 6-8, 10-11 and 26 meet the requirements of 35 U.S.C. §112, first paragraph, and that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejection of Claim 27. Accordingly, Appellant respectfully submits that the enablement and obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge the fee of $540.00 to Deposit Account No. 50-4498 in the name of Nestle Nutrition. The Director is authorized to charge any additional fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Respectfully submitted,

By:_____/gml/_____
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Dated: January 15, 2010

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/721,652

1. A composition comprising an oligosaccharide blend that comprises fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein (a) the composition comprises from about 15 g to about 20 g of the oligosaccharide blend; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.

6. The composition according to claim 1, wherein said composition provides at least 400 kcal per serving.

7. The composition according to claim 1, wherein the composition comprises more than about 1en % protein, based on the total caloric content of the composition.

8. The composition according to claim 1, wherein the composition is nutritionally complete.

10. The composition according to claim 1, wherein the composition comprises, per 100 ml: about 9 g proteins, about 22 g carbohydrates and about 9 g fats.

11. The composition according to claim 1, wherein the composition is a ready-for-consumption composition.

26. The composition according to claim 1, wherein the composition further comprises glutamine.

27. A composition comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein each of said FOS and GOS contains up to 95% by weight of said oligofructose and said oligogalactose that are composed of chains with a degree of polymerization ranging from about 2 to about 7 and wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.

EVIDENCE APPENDIX

EXHIBIT A: Non-Final Office Action mailed May 13, 2009

EXHIBIT B: Final Office Action mailed October 16, 2009

EXHIBIT C: U.S. Patent No. 6,399,124 to Lesens et al. ("*Lesens*")

EXHIBIT D: U.S. Publication No. 2003/0138476 to Van Leeuwen et al. ("*Van Leeuwen*")

RELATED PROCEEDINGS APPENDIX

None.